



VELLINTON HEALTHCARE

(Earlier Known as Texus Meditech)

Village Rampur Jattan, Trilokpur Road, Kala Amb, Dist. Sirmour.

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	: ARRYXIN Digoxin injection IP		
Batch No.	: GA24E-36C	Mfg. Date	: 05/2024
Batch Size	: 8000 Ampoules	Exp. Date	: 04/2026
Sample Qty.	: 60 Ampoules.	Analytical Report No.:	AFP20240268
Date of Receiving	: 23/05/2024	Date of Completion	: 06/06/2024
Neutral code no.	: HP/DRUGS/18-201-1585		

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless liquid solution filled in clear transparent glass ampoule.	A clear colourless liquid solution filled in clear transparent glass 4 ampoule.		
2.	Identification (By chemically)	A brown ring is produced at the interface and after a short time, an indigo colour is produced in the upper layer.	Complies		
3.	Uniformity of filled volume	Not less than nominal volume	Min: 2.0 ml Max: 2.1 ml		
4.	Average fill volume	Not less than 2 ml	2.04 ml		
5.	pH	Between (6.7 to 7.30)	6.91		
6.	Particulate Matter				
	≥ 10µm	NMT 6000 particles/Ampoule	Less than 6000 particles/Ampoule		
	≥ 25µm	NMT 600 particles/Ampoule	Less than 600 particles/Ampoule		
7.	Bacterial Endotoxins	NMT 200.0 Eu/mg of Digoxin.	Less than 200.0 Eu/mg of Digoxin.		
8.	Sterility	Should be Sterile	Sterile		
9.	Assay : Each ml contains:-				
Composition:		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Digoxin IP		250.0 mcg	245.23 mcg	98.09 %	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample submitted complies/does not complies with the prescribed standard/not standard of quality, as according to I.P. and IHS with respect to the above test only.

Analyzed By QC Officer	Checked By QC Executive	Approved By QC Manager/Incharge
Signature:- Date:- 06/06/2024	Signature:- Date:- 06/06/2024	Signature:- Date:- 06/06/2024

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